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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,796	09/22/2000	Wayne R. Curtis	99-2175	9738

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Intellectual Property Office
The Pennsylvania State University
113 Technology Center
University Park, PA 16802

EXAMINER

SORBELLO, ELEANOR

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/667,796

Applicant(s)

CURTIS, WAYNE R.

Examiner

Eleanor Sorbello

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of: /
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to amendment

1. Applicant's amendment filed January 24, 2002, paper number 7 has been entered. **Claims 1-20 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow.
2. Applicant's arguments are addressed below on a per section basis. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 1-20 stand rejected under 35 USC § 112, first paragraph as stated in office action dated 10/24/01 for reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that the examiner has the initial burden of providing an adequate and reasonable explanation as to why the claims are not adequately enabled by the disclosure. Applicants argue that the examiner has based her rejection on the fact that certain references allege "difficulty" in the area of the technology, and that while the specification provides certain examples and are thus enabled for the aforesaid, are not enabled for the full scope of the claims that are not exemplified in the specification. Examiner argues that enablement rejections are based on several factors, one of which is the state of the prior art and knowledge prevalent at the time of filing of the application with regards to that which is claimed. In the instant case, applicants argue that Goodman (U.S. 5,550,038) provides evidence that monocots and dicots are known to

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express mammalian peptides in plant cells. Examiner disagrees. Goodman only suggests that monocots and dicots may be used but only teach a method of producing mammalian peptides in dicotyledonous plant cells. Applicants argue that patent disclosures are not meant to be detailed production blueprints. Examiner agrees. However, examiner argues that because infecting monocotyledonous plants with viral replicons from T-DNA carrying a gene of interest, mediated by *Agrobacterium*, was not routine at the time of filing of the instant invention, and was subsequently taught by Baszczyński (U.S. 6,300,545 B1), issued October 9, 2001, it would definitely have required undue experimentation to make and use the invention as claimed, contrary to that argued by applicants. In this case, it would not only be mere routine experimentation, but undue trial and error experimentation because infecting monocotyledonous plants, according to the literature are cited to be very different from dicotyledonous plants. Applicant's claims also encompass infection of algal tissue by *Agrobacterium*. However as stated in the previous office action monocotyledonous plants have only been shown to be infected by *Agrobacterium* more recently, and algal tissues have not been shown to be infected thus far. Therefore, the burden is on the applicants to provide support for that which is claimed by providing details in the specification and examples to support the claims, in order to fill in the gaps not provided by the prior art. Therefore, applicants claims remain rejected due to the breadth of the claims, state of the prior art and guidance in the specification, because one of skill will require undue experimentation to make and use the invention as claimed.

Claim Rejections - 35 USC § 103

4. Claims 1-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US. Pat. Nos: 5,550,038), as stated in office action dated 10/24/01.
5. Claims 1, 13, 19, 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (US. Pat. Nos: 5,550,038) as applied to claims 1-18, in view of Baszczynski et al. (U.S. Pat. No: 6,303,341 B1), as stated in office action dated 10/24/01.

Applicants argue that their invention is novel because they claim (1) "transient" expression of the recombinant polypeptide after DNA introduction, without a requirement for selection of transformed transgenic cells where heterologous DNA is introduced into the plant chromosome and (2) wherein a nucleotide is delivered and expressed independent of its incorporation in the chromosome.

Examiner disagrees that the instant invention does not require incorporation into the genome. Examiner disagrees because it is an inherent property of a "binary vector" having T-DNA borders used in the instant invention, which are necessary for stable integration into the chromosome. (see specification page 8, lines 4, 5). "Transient" expression of the polypeptide is also an inherent feature when T-DNA binary vectors are administered to plants via an Agrobacterium. "Transient" expression is seen for a period of up to 12-18 hours. Subsequent to the transient expression, expression is seen when the T-DNA vector is integrated into the nuclear chromosome of the plant.

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Therefore, examiner disagrees with applicant's view that Goodman does not teach non-integration and the fact that expression of the heterologous DNA in the plant cell as taught by Goodman, requires months. Contrary to applicant's view, and as discussed above, Goodman and Baszczyński et al. teach all limitations claimed in the instant invention which are therefore rejected as being unpatentable over the two references cited in the statement of rejection.

Conclusion

6. Claims 1-20 remain rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

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Questions of formal matters can be directed to the patent analyst,

Patsy Zimmerman, whose telephone number is (703) 308-0009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 / 600

David T. Fox